Research Ethics Office

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April 14, 2008



St. Michael's Hospital A teaching hospital affiliated with the University of Toronto

Dr. Frances Silverman, Department of Occupational and Environmental Health, St Michael's Hospital

Dear Dr. Silverman,

REB# 05-143 - Cardiovascular Toxicity of Concentrated Ambient Fine, Ultrafine and Coarse

Particles in Controlled Human Exposures: Protocol #G4H10792 - Project 3

REB APPROVAL:

Original Approval Date

April 27, 2006

Annual/Interval Review Date

April 27, 2009

Thank you for your communications dated March 26, 2008 requesting an annual review and approval regarding the above named study.

This letter will serve as an extension of the St. Michael's Hospital (SMH) Research Ethics Board (REB) approval for the study for a period of 12 months effective from April 27, 2008 - April 27, 2009. Continuation beyond that date will require further review of REB approval.

During the course of this investigation, any significant deviations from the approved protocol and/or unanticipated developments or significant adverse events should immediately be brought to the attention of the REB.

The St. Michael's Hospital (SMH) Research Ethics Board (REB) operates in compliance with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, 2004, and ICH Good Clinical Practice Consolidated Guideline E6, Health Canada Part C Division 5 of the Food and Drug Regulations, Part 4 of the Natural Health Product Regulations, and the Medical Devices regulations. Furthermore, all investigational drug trials at SMH are conducted by Qualified Investigators (as defined in the latter document).

Good luck with your investigations.

With best wishes

Dr. Julie Spence Chair, Research Ethics Board Dr. Brenda McDowell

Vice Chair, Research Ethics Board

JS/BJM/dk

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